

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**Manufacturer of Controlled Substances; Notice of Application**

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on September 22, 2004 and October 29, 2004, Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in Schedule II.

Drug	Schedule
Dihydrocodeine (9120) .....	II
Remifentanyl (9739) .....	II
Sufentanyl (9740) .....	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the proposed registration.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative, Office of Liaison and Policy (ODLR) and must be filed no later than March 7, 2005.

Dated: December 21, 2004.

**William J. Walker,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**Importer of Controlled Substances; Notice of Application**

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2)(B) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on July 7, 2004, Chattem Chemicals Inc., 3801 St Elmo Avenue, Building 18, Chattanooga, Tennessee 37409, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the basic classes of controlled substances listed below:

Drug	Schedule
N-Ethylamphetamine (1475) .....	I
2,5-Dimethoxyamphetamine (7396) .....	I
4-Methoxyamphetamine (7411) .....	I
Difenoxin (9168) .....	I
Methamphetamine (1105) .....	II
Raw Opium (9600) .....	II
Concentrate of Poppy Straw (9670).	II

The company plans to import small quantities of the listed controlled substances for the manufacture of analytical reference standards.

Any manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections or requests for hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA **Federal Register** Representative, Office of Liaison and Policy (ODLR) and must be filed no later than February 3, 2005.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e) and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745-46), all applicants for registration to import a basic class of any controlled substances in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: December 21, 2004.

**William J. Walker,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration,*

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**Manufacturer of Controlled Substances; Notice of Registration**

By Notice dated July 21, 2004, and published in the **Federal Register** on August 10, 2004, (69 FR 48522), Dade Behring Inc., Route 896 Corporate Boulevard, Building 100, Attention: RA/QA, Post Office Box 6101, Newark, Delaware 19714, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances:

Drug	Schedule
Tetrahydrocannabinols (7370) .....	I
Ecgonine (9180) .....	II
Morphine (9300) .....	II

The company plans to produce the listed controlled substances in bulk to be used in the manufacture of reagents and drug calibrator/controls for DEA exempt products.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Dade Behring Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Dade Behring Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: December 21, 2004.

**William J. Walker,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

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